App. No. 10/521,234
Office Action Dated February 12, 2007

REMARKS

Reconsideration is respectfully requested in view of the above amendments and following remarks. Claims 1-7 have been canceled without prejudice or disclaimer. Claim 15 is new. The limitation in claim 15 concerning treating a sample containing the glycated protein with a protease in the presence of a sulfonic acid compound and in the absence of a tetrazolium compound is supported for example by Example 1 as described on page 14, line 15 to page 15, line 33. Claims 8-9 and 11-12 have been amended editorially. No new matter has been added. Claims 8-15 are pending.

Specification

Applicants respectfully submit that the two revisions to the second paragraph on page 16 are supported by the original disclosure. More specifically, the difference in absorbance of sample High and sample Low of the Comparative Example being as small as 0.7 is shown in Table 1 on page 16. Further, Table 1 shows the difference in absorbance of sample High and sample Low of the Example to be 17.0 mAbs, which is about twenty to thirty times more than that of the Comparative Example.

Withdrawal of the rejection is respectfully requested.

Claim rejections - 35 U.S.C. § 102

Claims 7-9 and 11-14 are rejected under 35 U.S.C. 102(e) a being anticipated by US Patent No. 6,790,665 (Yonehara et al.). Applicants respectfully traverse this rejection.

Claim 7 has been canceled. Claim 15 requires treating a sample containing the glycated protein with a protease in the presence of a sulfonic acid compound and in the absence of a tetrazolium compound (see Example 1 as described on page 14, line 15 to page 15, line 33). Conventional methods of protease treatment which do not employ a sulfonic acid compound usually involve about 6 to 40 hours of degradation time of the glycated protein in order to obtain polypeptide chains short enough for the fructosyl amino acid oxidase (FAOD) to act on the glycated portion of the polypeptide chains (see page 3, lines 2-7). However, when the protease treatment is conducted in the presence of a sulfonic acid compound, the degradation time is accelerated significantly (see page 3, lines 2-17), thereby allowing a high degradation efficiency. As a result, the accuracy of measurement is improved considerably (see page 16, lines 3-11 for example).

The effects of claim 15 are demonstrated in the experiments described in the Examples of the specification. Briefly, hemoglobin solutions with low and high concentrations were prepared (page 14, lines 26-35). The solutions were then treated with protease in the presence of a sulfonic acid compound at 37°C for five minutes (page 15, lines 19-22). The protease treatment was then followed by FAOD treatment for two and half minutes so as to allow a color development reaction (page 15, lines 22-26). The absorbance of the reaction solution was then measured (Id.). As shown in Table 1, the absorbance of both the low and high concentrations was much higher as compared to when the hemoglobin solutions were not treated in the presence of sulfonic acid (page 16). The results clearly indicate that the protease treatment in the presence of a sulfonic acid compound accelerates the degradation process and enhances accuracy of measurement.

Yonehara teaches treating a hemoglobin sample with a tetrazolium compound in the presence of a surfactant. However, Yonehara does not disclose treating a sample containing the glycated protein with a protease in the presence of a sulfonic compound and in the absence of a tetrazolium compound. Therefore, the reference does not anticipate claim 15. Further, although Yonehara discloses that an SLS method has been conventionally used for denaturing proteins, the reference also notes that such a method involves the addition of both SLS and a strong alkali in a sample, and the addition of these reagents influences enzymatic measurement systems involving the same sample for the measurement of substance other than hemoglobin (col. 1, lines 54-61). As such, the reference concludes that the SLS method makes serial measurements difficult (col. 1, lines 53-65), thereby teaching away from claim 15. Accordingly, claim 15 is patentable over Yonehara.

Claims 8-14 further limit and depend from claim 15. Therefore, claims 8-14 are patentable over the reference for at least the same reasons as claim 15.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

Claim rejections - 35 U.S.C. § 103

Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over European patent application, EP1 002874 A2 (Komori et al.) in view of Clin. Biochem. 1982, Vol. 15, No. 1, p. 83-88 (Oshiro et al.) and further in view of U.S. Patent No. 6,127,138 (Ishimaru et al.) and further in view of Blood, 1994, Vol. 83, No. 4, p. 1117-1123 (Johnson et al.). Applicants respectfully traverse this rejection.

Komori is directed to a method of measuring a glycated protein in a sample using a redox reaction by eliminating reducing substances. While Komori discloses that a surfactant can be used to hemolyze the whole blood itself, the reference also specifically notes the use of non-ionic surfactants such as the Triton series surfactants (paragraph [0044]). As such, the reference fails to specifically teach or suggest the use of an anionic surfactant such as SLS. The reference further teaches the addition of the tetrazolium compound to the sample treated with a non-ionic surfactant before the treatment with a protease (paragraph [0045]), thereby teaching away from claim 15.

The Examiner relies on Oshiro for the use of SLS. Oshiro does not cure the deficiencies of Komori. More specifically, the rejection contends that it would have been obvious to use SLS as taught by Oshiro in the method of measuring glycated hemoglobin as taught by Komori, because SLS is a surfactant known to be used in methods of measuring hemoglobin, and also has the advantage of not generating toxic waste. Applicants respectfully contend that the rejection's analysis of the references clearly has been tainted by the improper use of hindsight. As noted above, Yonehara teaches against the use of SLS during the protease treatment, and as such, the effects of claim 15 in fact would have been unexpected at the time the invention was made. Furthermore, nothing in Oshiro and Komori make any mention of using an anionic surfactant during the protease treatment. In fact, even if Komori and Oshiro are combined, the references merely teach the addition of a non-ionic surfactant before the addition of a tetrazolium compound. Therefore, the use of Oshiro is not substantiated by the reference itself.

Both Johnson and Ishimaru do not cure the deficiencies of Komori and Oshiro. Although Johnson discloses lowering reducing substances such as glutathione and Ishimaru discloses the use of a metalloprotease, the references fail to teach or suggest accelerating the degradation of glycated protein by a protease in the presence of a sulfonic acid compound. Therefore, claim 15 is patentable over the references, taken together or separately.

Claims 8-14 further limit and depend from claim 15. Therefore, claims 8-14 are patentable over the references for at least the same reasons as claim 15.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

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Double Patenting

Claims 7-14 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-22 of US Patent No. 6,790,665.

Claims 1-22 of Yonehara are directed to denaturing hemoglobin in a sample with a solution of a tetrazolium compound, and as such, do not recite treating a sample containing the glycated protein with a protease in the presence of a sulfonic acid compound and in the absence of a tetrazolium compound.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

Claims 7-14 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/517,853. The rejection is rendered moot, as Applicants submit herewith a Terminal Disclaimer to overcome the rejection. Applicants, however, do not concede the correctness of the rejection, and reserve the right to submit arguments with respect to any of the rejected claims at a later time.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully Submitted,

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Douglas P. Mueller
Reg. No.: 30,300
Hamre, Schumann, Mueller & Larson, P.C.
225 South Sixth Street, Suite 2650
Minneapolis, MN 55402
612.455.3800

DPM/ym